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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/537,535 | 06/03/2005 | Eric Thomas McAdams | 595552000100 | 4773 |

20872 7590 06/19/2009
MORRISON & FOERSTER LLP
425 MARKET STREET
SAN FRANCISCO, CA 94105-2482

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| EXAMINER |
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DANEGA, RENEE A

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| ART UNIT | PAPER NUMBER |
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3736

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| MAIL DATE | DELIVERY MODE |
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06/19/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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| Office Action Summary | Application No. 10/537,535 | Applicant(s) MCADAMS, ERIC THOMAS | |
| | Examiner Renee Danega | Art Unit 3736 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31,34-48,50,53-59 and 61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31,34-48,50,53-59 and 61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 31 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: how the circuit means is cooperating with the electrodes and where the electrical signal is coming from. Also missing is processor or similar means to create the map based on the electrical signals to bridge the gap between the circuit and display.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 31, 34-36, 39-44 and 46-47, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bloom et al. (US 6963772).

Bloom teaches a system for monitoring changes in a skin wound over time comprising a wound dressing (40) including a two dimensional rectangular array of at least 25 test electrodes (38) for application to the surface of the wound (4), circuit means for measuring an impedance of the tissue underlying each test electrode (78), and a

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display means (92) capable of presenting a visual map indicating the size and shape of the Bloom doesn't expressly teach presenting a visual map indicating the size and shape of the wound.

Bloom teaches the test electrodes arranged on a flexible backing of insulating material with the electrodes covered with a conductive gel inherently creating high resistance between the electrodes relative to the resistance to the underlying tissue (column 11, lines 5-21).

Bloom teaches the circuit means measures the electrical characteristic by applying an alternating electrical signal ad a plurality of frequencies between the test electrode and at least one other electrode applied to an organic body of which the tissue forms a part. The circuit measures the electrical characteristic by measuring voltage between each test electrode and an adjacent reference electrode also disposed on the flexible backing of insulating material in which a single electrode may be common to a plurality of test electrodes (column 9 ,lines 8-20, 39-50) (column 4, lines 47-65).

Bloom teaches the circuit comprising a first test electrode for providing a current source (4) integrated in the two-dimensional array of test electrodes, a second test electrode (10) for completing a current loop with the first electrode, and a third test electrode applied to tissue adjacent the first electrode (38's) (Figures 2D and 4)

5. Claims 37 and 48 rejected under 35 U.S.C. 103(a) as being unpatentable over Bloom as applied to claim 31 above, and further in view of Pearlman (US 6308097).

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Bloom teaches using a gel on the electrodes but doesn't expressly teach it to be hydrogel. However, Pearlman teaches an impedance measuring system in which the test electrodes are covered in hydrogel to enhance measuring signals (column 9, lines 39-52). It would have been obvious in view of Pearlman to use hydrogel as the gel in Bloom to enhance conductivity of the signals through the body.

Bloom teaches measuring impedance over a plurality of frequencies but doesn't expressly teach a range. However, Pearlman teaches measuring tissue anomalies by taking impedance measurements over a range of 1mHz to 100 kHz (column 21, lines 14-28). It would have been obvious in view of Pearlman to take impedance measurements in this range in Bloom to detect tissue anomalies.

6. Claims 50-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bloom et al. (US 6963772) in view of Kenan et al. (US 6788966).

Bloom teaches a method of monitoring changes in a skin wound over time comprising applying a dressing to the wound, the dressing including a two-dimensional array of at least 25 test electrodes applied to the surface of the wound; measuring an electrical characteristic of the tissue underlying each test electrode at various times; and presenting data about the wound (Figures 2c, 4, 5) (column 4, line 53-column 5, line 5).

Bloom doesn't expressly teach presenting a visual map indicating the size and shape of the wound. However, Kenan teaches an electrode array device for measuring skin impedance and displaying skin lesions in a visual map indicating size and shape (Figures 8, 9A). It would have been obvious in view of Kenan to provide visual maps of the wound in Bloom in order to visibly track the healing process.

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Bloom teaches the test electrodes arranged on a flexible backing of insulating material with the electrodes covered with a conductive gel inherently creating high resistance between the electrodes relative to the resistance to the underlying tissue (column 11, lines 5-21).

Bloom teaches the circuit means measures the electrical characteristic by applying an alternating electrical signal at a plurality of frequencies between the test electrode and at least one other electrode applied to an organic body of which the tissue forms a part. The circuit measures the electrical characteristic by measuring voltage between each test electrode and an adjacent reference electrode also disposed on the flexible backing of insulating material in which a single electrode may be common to a plurality of test electrodes (column 9 ,lines 8-20, 39-50) (column 4, lines 47-65).

7. Claims 38 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bloom as applied to claims 31 and 41 above, and further in view of Cudahy et al. (US 5184620).

Bloom teaches the leads (4) to be disposed on the flexible backing of insulating material with the electrodes (38) (Figure 4), but doesn't expressly teach the leads to be covered with an insulating material. However, Cudahy teaches the electrodes to be insulated by the pad from other conductors (column 6, lines 17-20). It would have been obvious in view of Cudahy to provide insulation over the leads in Bloom as well as the electrodes to prevent conductance between the wires.

Bloom doesn't expressly teach the reference electrode to be a test electrode as well. However, Cudahey teaches the reference electrode to be on the same backing and that

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during a given measurement an adjacent test electrode can act temporarily as its reference in order to provide the best impedance measuring results (column 7, lines 7-24). It would have been obvious in view of Cudahey to provide adjacent test electrodes to act as temporary reference electrodes in Bloom in order to eliminate false signals of wound detection and provide the best impedance measurement.

Response to Arguments

8. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

9. Applicant's arguments filed regarding the use of the Bloom reference have been fully considered but they are not persuasive. Applicant states that the Bloom reference doesn't teach measuring changes in a skin wound; however, the changes in fluid are directly correlated to the surface wound as disclosed as well as sites of inflammation (column 6, lines 47-53). Furthermore the reference points to the array to be a plurality of temperature or impedance sensors (column 8, lines 40-45). and claim 31 as written doesn't require the system to create a visual map from the measured electrical characteristics.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Danega whose telephone number is (571)270-3639. The examiner can normally be reached on Monday through Thursday 8:30-5:00 eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RAD

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736